

CORRECTION

Pepine CJ, Geller NL, Knatterud GL, et al. The Asymptomatic Cardiac Ischemia Pilot (ACIP) study: design of a randomized clinical trial, baseline data and implications for a long-term outcome trial. *J. Am Coll Cardiol* 1994;24:1-10.

Knatterud GL, Bourassa MG, Pepine CJ, et al. Effects of treatment strategies to suppress ischemia in patients with coronary artery disease: 12-week results of the Asymptomatic Cardiac Ischemia Pilot (ACIP) study. *J Am Coll Cardiol* 1994;24:11-20.

In the July 1994 issue of the Journal, the Asymptomatic Cardiac Ischemia Pilot (ACIP) Study Investigators published two reports, one on the design of the study and the other on the 12-week results of the ACIP Study. As part of the final editing of the data, the Clinical Coordinating Center staff discovered inconsistencies in the reporting of baseline characteristics in one clinical unit. As a result, an audit visit was conducted, and the records for all 60 patients enrolled in this clinical unit were examined. The audit determined that there was evidence of unacceptable performance in the conduct of the trial at this unit. Briefly, a number of the enrolled patients were not eligible to be randomized, and treatment plans were frequently made for patients before randomization and followed irrespective of randomized treatment assignment. The

conclusion was that the data from this unit were not of acceptable quality and that the data from this unit could not be considered comparable to the data from the other clinical units. Therefore, the audit team recommended that no data from this clinical unit should be included in future analyses or publications. The ACIP Data and Safety Monitoring Board reviewed the audit report without knowledge of the Audit Committee recommendation and came to the identical conclusion.

All analyses presented in the two reports published in July 1994 have been repeated excluding patients from this clinical unit. We found that there were essentially no changes in the reported findings (Table 1). Thus, the conclusion in the 1994 ACIP report by Knatterud et al. that the pilot study demonstrated that cardiac ischemia can be suppressed in 40% to 55% of patients with either low or moderate doses of medication or revascularization and that a large trial is feasible are still valid.

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Table 1. ACIP Outcomes

	11 Clinical Units				10 Clinical Units			
	Angina-Guided Strategy	Ischemia-Guided Strategy	Revasc	p Value	Angina-Guided Strategy	Ischemia-Guided Strategy	Revasc	p Value
No. of pts enrolled	204	202	212		183	183	192	
Primary outcome (no ischemia or events)								
12 wk	38.9	41.3	54.7	0.004	38.6	41.4	53.6	0.01
6 mo	39.8	43.0	55.9	0.003	39.2	41.5	54.9	0.005
12 mo	31.8	37.0	57.3	< 0.001	30.9	35.6	56.7	< 0.001
Death or MI								
12 wk	1.5	1.0	1.9	0.74	1.6	1.1	2.1	0.74
6 mo	4.4	4.0	1.9	0.33	3.8	4.4	2.1	0.46
12 mo	8.8	5.9	2.4	0.02	8.8	6.0	2.6	0.04
Death, MI, PTCA or CABG								
12 wk	5.9	3.0	5.2	0.35	4.4	2.7	5.2	0.46
6 mo	10.3	7.9	7.5	0.56	8.2	8.2	7.8	0.99
12 mo	17.2	14.4	9.9	0.10	15.9	13.7	9.9	0.26

Data presented are number or percent of patients (pts). CABG = coronary artery bypass graft surgery; MI = myocardial infarction; PTCA = percutaneous transluminal coronary angioplasty; Revasc = revascularization.